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TO RUEHC/SECSTATE WASHDC PRIORITY 1048  
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RUEHCV/AMEMBASSY CARACAS PRIORITY 1284  
RUEHLP/AMEMBASSY LA PAZ FEB 5043  
RUEHPE/AMEMBASSY LIMA PRIORITY 4937  
RUEHMN/AMEMBASSY MONTEVIDEO PRIORITY 3541  
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STATE FOR EB/TPP/IPE - JENNIFER BOGER  
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E.O. 12958: N/A

TAGS: [ETRD](#) [KIPR](#) [PREL](#) [CI](#)

SUBJECT: CHILE: POST RECOMMENDS CHILE REMAIN ON PRIORITY  
WATCH LIST

REF: A. STATE 7944

[1](#)B. 06 SANTIAGO 1761

[1](#)C. SANTIAGO 174

[1](#)D. SANTIAGO 141

[1](#)1. (SBU) Summary: Post recommends Chile remain on the Special 301 Priority Watch List in 2007. During 2006, Chile was the subject of an Out-of-Cycle Review (OCR). The result of the OCR was USTR's announcement on January 8, 2007 placing Chile on the Priority Watch List. In the intervening month, Post has not seen enough positive movement on intellectual property rights (IPR) issues -- despite some hasty enforcement actions and a host of IPR-related bills put before the Chilean Congress -- to warrant changing Chile's status. The root of the problem remains the lack of a clear national policy on IPR protection. End Summary.

New Member of Priority Watch List

[1](#)2. (SBU) In 2006, the third year of the U.S.-Chile Free Trade Agreement (FTA), Chile was the subject of an Out-of-Cycle Review (OCR) due in large part to its failure to fulfill many of its FTA commitments on intellectual property rights (IPR). The OCR, announced in April 2006, resulted in an intensified dialogue between U.S. and Chilean officials on IPR issues. The exchanges included digital video conferences, additional Embassy reporting and a visit to Santiago in August 2006 by Assistant USTR Everett Eissenstat. Despite repeated USG efforts to understand the progress Chile claimed it had made (ref B) to improve IPR protection, the GOC was unable to lay out in a comprehensible manner its framework to protect IPR. The GOC's handling of key technical issues such as protection for clinical data and patents remain unclear. There was also evidence that film, music and software piracy is growing worse in Chile. On January 8, 2007, USTR announced the results of the OCR and placed Chile on the Priority Watch List.

Data Protection and Patent Linkage

[1](#)3. (SBU) In 2006, there was no progress on core issues such as data protection and patents related to pharmaceutical

products. Despite new legislation and implementing regulations from 2005, Chile continued to grant approval for generic copies, violating patents for innovative pharmaceuticals. Additionally, the GOC allowed local companies seeking market access to use exclusive company data from European and North American companies as the scientific basis for approving these generic copies. Local representatives of international pharmaceutical companies continued to detail violations of exclusive company test data in the Chilean drug approval process. On the issue of patents, there was no linkage between granting market access and the existence of valid patents. The GOC played a semantic game by arguing that its FDA-equivalent, the Instituto de Salud Publica (ISP), only granted "sanitary approval" and thus did not violate the FTA's provision barring the granting of marketing approval in violation of a patent holder's rights. Internal documentation publicly submitted by the GOC as part of a judicial case demonstrated that even it could not distinguish between sanitary approval and marketing approval, making its semantic shell game appear even more disingenuous.

#### Step Forward Becomes A Step Backward

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¶4. (SBU) In July 2006, the ISP issued an internal regulation, which required any company seeking approval for a biotech product to submit its own proprietary clinical test data. This decision was never trumpeted by the GOC as an advance in IPR protection and the Embassy noticed it only through the GOC's online public gazette. When the Embassy contacted local representatives of the international pharmaceuticals, all engaged in biotech development worldwide, they saw the ISP's decision as an important step toward better IPR

protection in Chile.

¶5. (SBU) What was a step forward became a step backward before the end of the year, however, because in December 2006, Minister of Health Barria overruled the ISP's internal regulation with her own decree carrying the force of law. Barria decided that even for biotech products it was not/not necessary for a company to present its own proprietary clinical data when seeking sanitary/marketing approval. A company could present data from any source, including proprietary data from another company, as it sought sanitary/marketing approval for its product in Chile.

#### No Policy on IPR

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¶6. (SBU) The core issue at the heart of IPR-related issues in Chile is the lack of a clear, enforceable government policy. With a strong presidential system in place, individual ministries cannot on their own make policy on IPR. If it is to emerge at all, that unambiguous direction must come from President Bachelet. Though the judiciary is independent, it also understands there is no clear policy direction on the issue. So, it manages either to drag out court cases so long that a decision is OBE for the IPR stakeholders, or to find unrelated technical reasons for dismissal. The efforts of the judiciary to avoid setting precedence in IPR cases have been noticed in a number of different areas. In addition to familiar cases in Santiago largely involving pharmaceutical products, we have also learned of cases involving pirated products being dismissed by judges in Chile's free trade zone in Iquique. Judges have dismissed cases either on technical grounds or with spurious arguments that the goods were only "transiting" Chile, and thus were not its responsibility.

#### Some Flash in Anti-Piracy Efforts

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¶7. (SBU) In the immediate aftermath of annual talks under the FTA (ref C), there was a burst of activity on the anti-piracy front. Illegal copies of music, movies and books were seized, which made some headlines. As opposed to the GOC's public stance defending its position on data protection and

patents, Foreign Minister Foxley promised the Ambassador more action to fight piracy, saying Chile's position was indefensible and it needed to do more (ref D). However, evidence from industry and anecdotal evidence in Santiago and elsewhere suggest that nothing has sustainably changed. The market for legal copies of products contracted, as piracy gained ground throughout 2006. Efforts by Chilean police and prosecutors have had little real impact as fines are minimal, with most IPR violators not even paying them and criminal penalties suspended. With little to nothing to show for the effort, police rarely investigate the manufacturing and distribution of pirated materials.

18. (SBU) There are also several bills before Congress, which attempt to address Chile's remaining legal FTA-related obligations on trademarks and patents. It is impossible to predict when the legislation will pass and more importantly, when and how seriously it will be implemented. There is also a bill before Congress to join the Patent Cooperation Treaty, another FTA obligation and one Chile was to have fulfilled by January 2007. The Minister of Economy has introduced plans to reform the Department of Industrial Property (Chile's equivalent of the U.S. Patent and Trademark Office), but it remains unclear what the final outcome will be and how patent office reform could improve IPR protection.

Recommendation: Maintain Chile on the Priority Watch List  
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19. (SBU) Chile's policy decisions and actions continue to fall far short of its rhetoric and trade agreement commitments on IPR. Worse still, the few legislative and regulatory moves that the GOC has initiated may not be improvements at all; they may just be a legalistic effort to check the required boxes. While the GOC continues to provide

assurances that it understands USG concerns on patents and copyrights and is moving to address them, the reality on the ground is quite different. Post believed it had no choice at the conclusion of the OCR but to recommend Chile be placed on the Priority Watch List. Reality in Chile has differed from rhetoric long enough. It was high time to say the emperor had no clothes. This has not changed.

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